

Sub 57
Sub 22
tip

We claim:

1. A device for collecting a sample of a biological fluid comprising:
 - (a) one or more hollow or porous microneedles having a base end and a tip,
 - (b) a substrate to which the base of the microneedle is attached or integrated, and
 - (c) at least one collection chamber which is selectably in fluid communication with the base end of the microneedle.
2. The device of claim 1 further comprising
 - (d) a means for inducing transport of the biological fluid or component thereof into the collection chamber.
3. The device of claim 2 wherein the pressure within the collection chamber can selectively be reduced.
4. The device of claim 3 wherein the pressure reduction is induced by expanding the internal volume of the collection chamber.
5. The device of claim 4 wherein the collection chamber is a standard or Luer-lock syringe.
6. The device of claim 3 wherein the collection chamber comprises an upper portion which is formed of a material which is deformable.
7. The device of claim 3 further comprising a plunger movably secured to the substrate, wherein the plunger can deform the collection chamber.
8. The device of claim 6 further comprising a one-way valve.
9. The device of claim 1 wherein the collection chamber comprises a plurality of compartments.
10. The device of claim 1 comprising a three dimensional array of microneedles.
11. The device of claim 1 further comprising an adhesive material for securing the device to the biological barrier surface during fluid withdrawal or sensing.

12. The device of claim 1 further comprising a means for controlling flow through the microneedle.

13. The device of claim 12 wherein the means for controlling flow is a fracturable or removable barrier which is interposed between the collection chamber and base of the microneedle.

14. The device of claim 1 further comprising a sensor in communication with the collection chamber.

SJK 7 15. A device for sensing an analyte in a biological fluid, the device comprising:

- (a) one or more microneedles having a base end and a tip,
- (b) a substrate to which the base of the microneedle is attached or integrated,
- (c) at least one sensor which is selectably in communication with the microneedle.

16. The device of claim 15 wherein the sensor comprises a chemical or biochemical agent that react with the analyte, and electrochemical or optical transducers which measure the reaction of the agent and analyte.

17. The device of claim 16 wherein the agent is an enzyme selected from the group consisting of glucose oxidase, glucose dehydrogenase, and combinations thereof.

18. The device of claim 15 further comprising an electronics package in communication with the sensor.

19. The device of claim 15 for insertion of the microneedles in skin and sensing of glucose.

SJK 7 20. A device for sensing an analyte in a biological fluid, the device comprising:

- (a) one or more microneedles having a base end and a tip,
- (b) a substrate to which the base of the microneedle is attached or integrated,

wherein at least one of the microneedles is or comprises a sensor.

21. The device of claim 20 wherein the sensor comprises a chemical or biochemical agent that react with the analyte, and electrochemical or optical transducers which measure the reaction of the agent and analyte.

22. The device of claim 20 further comprising an electronics package in communication with the sensor.

23. The device of claim 20 for insertion of the microneedles in skin and sensing of glucose.

24. The device of claim 1 wherein the collection chamber is adapted to receive and use glucose strips.

25. The device of claim 1 wherein the microneedle is hollow and comprises at least one opening in the side of the microneedle.

26. The device of claim 1 wherein the microneedle has a hollow bore containing a material to modulate the flow of biological fluid through the microneedles into the collection chamber.

Sub 10 27. A method for collecting a sample of a biological fluid or analyte therein, comprising the steps:

providing a device comprising (i) one or more hollow or porous microneedles having a base end and a tip, (ii) a substrate to which the base of the microneedle is attached or integrated, (iii) at least one collection chamber which is selectably in fluid connection with the base end of the microneedle, and (iv) a means for inducing transport of the biological fluid or component thereof into the collection chamber;

inserting the microneedles into a biological barrier comprising biological fluid; and

triggering the induction means to permit the transport of the biological fluid or a component thereof through the microneedles and into the collection chamber.

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Art 2

28. The method of claim 27 wherein the induction means is selected from capillary action, diffusion, mechanical pumps, electroosmosis, electrophoresis, convection, and combinations thereof.

29. The method of claim 27 wherein the induction means utilizes a pressure gradient in which the pressure within the microneedles and/or collection chamber is less than the pressure of the biological fluid adjacent the tip of the microneedle.

30. The method of claim 27 wherein the analyte to be collected or sensed is selected from the group consisting of glucose, cholesterol, bilirubin, creatine, metabolic enzymes, hemoglobin, heparin, clotting factors, uric acid, tumor antigens, reproductive hormones, oxygen, pH, alcohol, tobacco metabolites, and illegal drugs.

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31. A method sensing an analyte in a biological fluid, comprising the steps:

(a) providing a device comprising (i) one or more hollow or porous microneedles having a base end and a tip, (ii) a substrate to which the base of the microneedle is attached or integrated, and (iii) at least one sensor which is in communication with one or more of the microneedles;

(b) inserting the microneedles into a biological barrier comprising biological fluid; and

(c) contacting the sensor with the biological fluid.

32. The method of claim 31 wherein the device further comprises (iv) at least one collection chamber which is selectably in fluid connection with the base end of the microneedle, and (v) a means for inducing transport of the biological fluid or component thereof into the collection chamber, and

wherein, after step (b), the induction means is triggered to draw the biological fluid or a component thereof through the microneedles and into the collection chamber.

33. The method of claim 32 wherein the induction means utilizes a pressure gradient in which the pressure within the microneedles and/or

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collection chamber is less than the pressure of the biological fluid adjacent the tip of the microneedle.

34. The method of claim 33 wherein the pressure gradient is created by increasing the volume within the collection chamber.

35. The method of claim 31 wherein the analyte to be collected or sensed is selected from the group consisting of glucose, cholesterol, bilirubin, creatine, metabolic enzymes, hemoglobin, heparin, clotting factors, uric acid, tumor antigens, reproductive hormones, oxygen, pH, alcohol, tobacco metabolites, and illegal drugs.

36. The method of claim 27 for sensing glucose wherein the biological barrier is human skin.

37. The method of claim 31 for sensing glucose wherein the biological barrier is human skin.

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